



Qualified Presumption of Safety (QPS) an EFSA Tool for Microbial Safety Assessment

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USP-IFT Workshop on Identity and Characterization of a Probiotic Microorganism used as a Food Ingredient: Importance to Safety and Efficacy

May 9-10, 2012

USP Meetings Center • Rockville, Maryland

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Title of Presentation: Qualified Presumption of Safety (QPS) – an EFSA Tool for Microbial Safety Assessment

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Main Abstract Body:

- Not to exceed 500 words
- Statement of purpose, research methodology, results and benefits

Statement of purpose

EFSA is requested to assess the safety of a broad range of biological agents (including microorganisms and viruses) in the context of notifications for market authorisation as sources of food and feed additives, enzymes and plant protection products. Some of these have a long history of apparent safe use, while for others the available body of knowledge is more limited and they might represent a risk for consumers. In this context, the Qualified Presumption of Safety (QPS) concept was implemented within EFSA as a harmonized approach to simplify this safety assessment where possible [1].

In 2002/3 a working group consisting of members of the former Scientific Committees on Animal Nutrition, Food and Plants of the European Commission (EC) proposed the introduction of a Qualified Presumption of Safety (QPS) approach for selected microorganisms. In April 2003, responsibility for the safety assessments of food/feed undertaken by the Scientific Committees of the EC was formally transferred to the European Food Safety Authority (EFSA) following Regulation EC 178/2002. In 2007, the Scientific Committee of EFSA recommended that a QPS assessment for microorganisms should be implemented across EFSA and applied equally to all safety considerations of microorganisms intentionally added to the food and feed chain that EFSA is required to assess. The Scientific Panel on Biological Hazards (BIOHAZ) took up the task of carrying out an annual review of the QPS list in 2008 [2, 3].

Methodology

The qualified presumption of safety (QPS) assessment was implemented by EFSA for its own use to provide a generic risk assessment approach applicable across EFSA's scientific Panels, for biological agents notified for intentional use in the whole food chain. The safety of unambiguously defined biological agents at the highest taxonomic unit that is appropriate for the purpose for which an application is intended and the completeness of the body of knowledge are assessed. Identified safety concerns for a taxonomic unit are where sensible reflected as

'qualifications' when a recommendation for the QPS list is given. The list of QPS recommended biological agents is reviewed and updated annually. Therefore, the only valid list is the one in the most recent scientific opinion [1,2].

Results and benefits

The QPS approach has been successfully applied within EFSA to undertake the formal safety assessment of notified microorganisms and it has been appreciated as a common sense approach by risk assessors, stakeholders and risk managers and applicants. Since its introduction at the end of 2007, EFSA's Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has been the main user, and has increasingly benefitted from the QPS assessment when carrying out risk assessments in the context of authorization request for additives for use in animal nutrition [1,2].

References: if applicable

(Insert references here or on a separate page)

1. EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2011 update). EFSA Journal 2011;9(12):2497. [www.efsa.europa.eu/en/efsajournal/pub/2497.htm].
2. Leuschner RGK, Robinson TP, Hugas M, Cocconcelli PS, Richard-Forget F, Klein G, Licht TR, Nguyen-The C, Querol A, Richardson M, Suarez JE, Thrane U, Vlak JM and von Wright A, 2010. Qualified presumption of safety (QPS): a generic risk assessment approach for biological agents notified to the European Food Safety Authority (EFSA). Trends Food Sci. Technol. 21, 9, 425-435. Corrigendum: Trends Food Sci. Technol. 22(2011), 51-52.
3. EFSA website topic on Qualified presumption of safety (QPS): www.efsa.europa.eu/en/topics/topic/qps.htm

ABSTRACTS DUE April 20, 2012.

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